510(k) Summary of Safety and Effectiveness

K003796

The following information provides data supporting a substantially equivalent determination between the ADVIA 120 cerebrospinal fluid (CSF) method and the manual microscopic predicate method.

Intended Use

The ADVIA 120 cerebrospinal fluid (CSF) cell count is intended to provide an *in vitro* diagnostic, quantitative determination of blood cells in CSF specimens. The ADVIA 120 provides leukocyte (WBC) and erythrocyte (RBC) counts along with both absolute and proportional counts for the WBC differential.

Device Description

The ADVIA 120 CSF Method consists of the following: An analytical module that aspirates, dilutes, and analyzes CSF samples. A computer workstation that controls the instrument, provides the primary user interface with the instrument, and manages the data produced by the instrument. A printer that optionally generates reports based on the instrument results.

The following parameters are reported with the ADVIA 120 CSF method:

White Blood Cell Parameters
WBC - white blood cell count
Neut - neutrophil count (percentage and absolute counts)
Lymph - lymphocyte count (percentage and absolute counts)
Mono - monocyte count (percentage and absolute counts)
MN – mononuclear count (percentage and absolute counts)
PMN – polymorphonuclear count (percentage and absolute counts)

Red Blood Cell Parameters
RBC - red blood cell count

Principles of Operation

The principles of operation of the ADVIA 120 CSF method are similar to the ADVIA 120 method for counting cells in whole blood.

The WBC parameters are derived through a combination of laser light scatter for the WBC count, along with light scatter and absorption based on cellular peroxidase activity from a tungsten light source for the WBC differential.

The RBC count is derived from low and high angle laser light scattering properties used to classify cells based on volume and refractive index.

Similarities and Differences between the ADVIA 120 CSF Method and the Pre-Amendment Predicate Method

The following table provides similarities and differences between the ADVIA 120 CSF method and the manual microscopic predicate method.

Similarities/Differences	Characteristic	Manual Method	ADVIA 120 Method
Similarities	Intended Use	To provide a quantitative determination of blood cells in CSF specimens.	Same as manual method.
	Specimen Analyzed	CSF collected in a sterile specimen tube.	Same as manual method.
Differences	WBC Count	Manual cell count performed in a counting chamber by a skilled competent technologist.	Automated count.
	RBC Count	Manual cell count performed in a counting chamber by a skilled competent technologist.	Automated count.
	WBC Differential	Cytocentrifugation followed by Wright or Wright-Giemsa staining with counts by a skilled competent technologist.	Automated count.

Conclusion

The test results included in this submission demonstrate that the ADVIA 120 CSF method has equivalent accuracy, precision, linearity, sensitivity and specificity to the manual microscopic predicate method.

Date 12/6/00

Fredrick Clerie
Director Regulatory Affairs
Bayer Corporation
511Benedict Avenue
Tarrytown, New York 10591-5097

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 5 2001

Mr. Fredrick Clerie
Director, Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K003796
Trade Name: ADVIA 120 Hematology System
Regulatory Class: II
Product Code: GKZ
Dated: December 6, 2000
Received: December 8, 2000

Dear Mr. Clerie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003796

Device Name: **ADVIA 120 Hematology System**

Indication For Use:

The ADVIA 120 Hematology System is a quantitative, automated hematology analyzer that provides a leukocyte differential count and reticulocyte analysis in whole blood and cerebrospinal fluid (CSF) specimens for *in vitro* diagnostic use in clinical laboratories. The CSF method is used on CSF samples with RBC counts greater than 1,000 cells/μL, WBC counts less than or equal to 5 cells/μL or greater than 10 cells/μL, and a proportional WBC differential for samples with WBC counts greater than 20 cells/μL.

Peter E Maksim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003796

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Optional Formal 1-2-96